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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,031	12/11/1998	ATTILA T. LORINCZ	2629-4005US1	6182

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/210,031	TANG ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50* is/are allowed.

6)☒ Claim(s) *36-49 and 51-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 August 2003 has been entered.

Drawings

2. The drawings filed 27 August 2003 have been accepted.

Claim Objections

3. The objection to claim 56 in the Office action mailed 28 April 2003 is withdrawn in view of the amendment filed 27 August 2003.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 36-48, 51-54, 58, 59, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy.

The claims are drawn to cell collection medium comprising alcohol, a cross-linking agent, and a chelator. In some embodiments the medium is buffered at neutral or acidic pH levels. In some embodiments particular volumes of medium are claimed, and medium that inhibits RNA, DNA, or protein degradation is claimed.

Dunphy shows in example 4, columns 7 and 8, a medium for fixing tissue for histological procedures. The aqueous medium comprises 3.5-4% ethanedial, a cross-linking fixative, and 15-25% ethanol. Dunphy shows in column 5, lines 1-7 that a chelating agent EDTA is a useful addition because it acts as a bacteriostatic agent and because it inhibits bacterial enzymatic activity. Dunphy shows that is desirable to add a buffering agent in column 6 to buffer to pH 6.8-7.8, and further shows to use media with an acidic pH in column3, lines 18-19 and column 4, lines 16-18. Dunphy does not explicitly show a medium for tissue collection that comprises EDTA, or is buffered to neutral or acidic pH levels.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tissue collection medium of Dunphy in example 4 by addition of buffer and EDTA, because Dunphy shows that buffering agents may be used to adjust the pH to neutral or acidic levels for tissue fixation media as desired, and because Dunphy shows that EDTA has a bacteriostatic effect that is desirable in a tissue fixation medium. It would have been further obvious to use any of the recited volumes of medium in the claims as dictated by the size of the tissue sample. It would have been further obvious that inhibition of bacterial enzymatic activity by EDTA and cross-linking agents would inhibit enzymatic degradation of RNA, DNA, and protein.

8. Claims 36, 37, 42, 49, 55-60, and 68-75 are rejected under 35 U.S.C.§103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison.

The claims are drawn to tissue collection media comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, and their methods of use.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show methods of using tissue treated in collection medium of DNA and protein analysis. Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show cross-linking agents consisting of formaldehyde or glutaraldehyde.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be uses in in situ antigen assays.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use tissue samples treated with the collection medium of Dunphy for methods of DNA and antigen analysis because Weber shows that such media can be used for DNA hybridization analysis and Harrison shows that such media may be used for antigen analysis. It would have been further obvious to use a cross-linking agent consisting of formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

9. Claims 58, 59, and 62-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Wainwright.

The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above does not show a container comprising collection medium as claimed in claims 58 or 59, a lid, and a brush.

Wainwright shows a container, a lid fitting the container, and a brush for preserving a cell sample and comprising a pap unit.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the container of Wainwright with the tissue collection medium of

Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above because Wainwright shows that such containers are convenient for obtaining pap samples for subsequent analysis.

10. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above and further in view of Wainwright as applied to claims 58, 59, and 62-66 above, and further in view of Weber in view of Harrison.

The claims are drawn to containers comprising collection medium as claimed in claims 58 or 59 further comprising a cross-linking agent consisting of formaldehyde or glutaraldehyde, a lid, and a brush.

Weber et al. shows on page 8 a tissue collection medium useful for in situ hybridization studies. Weber et al. shows that the medium may comprise a cross-linking fixative at a level of less than 10%, and suggests use of formalin (formaldehyde) as a cross-linking fixative.

Harrison shows discloses a tissue collection medium comprising glutaraldehyde as a cross-linking fixative at a level up to 1%. Harrison shows in column 4 that tissue treated in collection medium may be uses in in situ antigen assays.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the container comprising tissue collection medium of Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright as applied to claims 58, 59, and 62-66 above by use of cross-linking agents consisting of formaldehyde or glutaraldehyde because Weber and Harrison respectively show that such aldehydes are useful cross-linking agents in tissue collection media that are compatible with further analysis of DNA or protein.

11. Applicant's arguments filed 27 August 2003 have been fully considered but they are not persuasive. The applicants point to intended use limitations in the claims and argue that the applied prior art does not show such limitations. However, intended use limitations that do not affect the structure of the claimed compositions are not given patentable weight (see MPEP 2111.02). The applicants have not provided evidence that the compositions obvious over the cited prior art do not meet the limitations of the preamble of the claims and the rejections are maintained. The applicants state that claim 67 is not obvious because Weber discloses reagents that are incompatible with protein analysis, however claim 67 is not limited to protein analysis.

Double Patenting

12. The provisional rejection of claims 36-74 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/598571 in view of Weber et al. (WO 94/02645, cited in the Form PTO 1449 received 07 June 1999) in view of Harrison is withdrawn in view of the abandonment of copending Application No. 09/598571.

Allowable Subject Matter

13. Claim 50 is allowable.

Conclusion

14. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb